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09/772,134	01/29/2001	David A. Lightfoot	1268/4/2	9557

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,134

Applicant(s)

LIGHTFOOT ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 27-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-26 and 71-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4,13&15. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group VI, claims 11-26 and 71-80, in Paper No. 16, filed 16 January 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-10 and 27-70 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 16.
3. This application contains claims 1-10 and 27-70 drawn to an invention nonelected with traverse in Paper No. 16. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Information Disclosure Statement

5. The information disclosure statements filed 2 July 2001, 27 August 2001, 15 January 2002 and 16 January 2003 have been considered, a signed copy of each is

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attached hereto. The IDS filed 15 January 2002 and the IDS filed 16 January 2003 are duplicative.

Specification

6. The abstract of the disclosure is objected to because it is not descriptive of the claimed subject matter and is not in proper English, the present abstract is a sentence fragment. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 58, line 7. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

8. Claims 25 and 26 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims are directed to a different scope than that of claim 23, upon which they depend, because at claim 25 there is no indication that the transgenic plant comprises the nucleic acid molecule of claim 23, only a component of the claimed nucleic acid molecule comprising an isolated soybean *Rhg4* gene.

9. Claims 26, 71, 72 and 74 is objected to because of the following informalities:

At claim 26, the phrase "a plant" should read -- the transgenic plant -- in referring to claim 25.

At claim 71, line 2 the phrase "introducing to" should read -- introducing into --.

At claim 72, line 2, the phrase "vector or" should read -- vector and --.

At claim 74(a), the word -- and -- should be inserted after the semicolon.

At claim 79, line 5, the phrase "resistance or" should read -- resistance and --.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 11-26 and 71-80 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

Applicant claims a nucleic acid molecule encoding a biologically active SCN/SDS resistance polypeptide, a transgenic host cell comprising said nucleic acid molecule and a transgenic plant comprising said nucleic acid molecule. Applicant further claims that said nucleic acid molecule comprising the nucleotide sequence of any of SEQ ID NO: 13 and a method comprising introducing into a plant a construct comprising a nucleic acid sequence encoding an SCN/SDS resistance gene encoding a protein having the amino acid sequence of SEQ ID NO: 14.

Applicant asserts that the nucleotide sequence of SEQ ID NO: 13, that encodes the amino acid sequence of SEQ ID NO: 14, encodes the soybean *rhg1* gene for soybean cyst nematode resistance (page 40, 1st paragraph of the specification).

Applicant asserts that the amino acid sequence of SEQ ID NO: 14 has high homology to

the *Arabidopsis thaliana* T18N14.120 protein (Accession Number T46070), a putative protein kinase, and to the rice Xa21 disease resistance gene encoding a lucine-rich repeat protein (page 40, lines 9-16 of the specification). The Examiner notes that SEQ ID NO: 13 comprises undefined nucleic acids within the sequence. Hence, it would require additional experimentation to isolate the complete coding sequence and to confirm the function of the claimed isolated nucleic acid as claimed. In addition the art teaches that SCN resistance associated with the locus *rhg1* on linkage Group G is a recessive gene (claims 13-16, 73, 74 and 77), which in the meaning of the art is that said locus comprises a nonfunctional gene either not expressed or encodes a nonfunctional protein (see Rao-Arelli *et al* 1992, Crop Science 32:862-864). Hence, it is unclear from the teachings of the instant specification what utility a recessive gene would have to one of skill in the art in a method of making a transgenic plant as claimed in the elected invention.

See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 11-26 and 71-80 are also rejected under 35 U.S. § C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and use the claimed invention.

Applicant claims a nucleic acid molecule encoding a biologically active SCN/SDS resistance polypeptide, a transgenic host cell comprising said nucleic acid molecule and a transgenic plant comprising said nucleic acid molecule. Applicant further claims that said nucleic acid molecule comprising the nucleotide sequence of any of SEQ ID NO: 13 and a method comprising introducing into a plant a construct comprising a nucleic acid sequence encoding an SCN/SDS resistance gene encoding a protein having the amino acid sequence of SEQ ID NO: 14.

Applicant teaches an isolated nucleic acid having the sequence of SEQ ID NO: 13 and a polypeptide having the amino acid sequence of SEQ ID NO: 14.

Applicant does not teach an isolated and purified nucleic acid molecule encoding a biologically active SCN/SDS resistance peptide.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant's guidance for identifying and isolating a nucleic acid encoding an SCN/SDS resistance polypeptide is very limited (see page 119 of the specification). Neither the nucleic acid sequence of SEQ ID NO: 13 nor the amino acid sequence of SEQ ID NO: 14 appear to teach a SCN/SDS resistance gene, and the representative *rhg1* partial cDNA set forth as SEQ ID NO: 122 does not teach such a gene (see page 40, lines 18-19). Additionally, at claims 23 and 25, Applicant claims a nucleic acid molecule further comprising an isolated soybean *Rhg4* gene capable of conveying *Heterodera glycines*-infestation resistance that is located within a quantitative trait locus and a transgenic plant comprising said isolated soybean *Rhg4* gene, but Applicant does not teach such a nucleic acid molecule, only how to possibly isolate such a nucleic acid. The art teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proven in experiments designed to evaluate that function (see Duggleby 1997, Gene 190:245-249, page 248, left column, last paragraph). At claims 71-79, Applicant does not teach how to use the claimed method for providing a resistance trait to a plant other than soybean, because the construct used in the claimed method would not have a functional use in any other plant than soybean. In addition the art teaches that SCN resistance associated with the locus *rhg1* on linkage Group G is a recessive gene (claims 13-16, 73, 74 and 77), which in the meaning of the art is that said locus comprises a nonfunctional gene either not expressed or encodes a nonfunctional protein (see Rao-Arelli *et al* 1992, Crop Science

32:862-864; and Meksem *et al* 2001, Theoretical and Applied Genetics 103:710-717, page 711, left column, 1st paragraph).

Hence, given the limited guidance by Applicant, the lack of working examples, especially for transgenic plant at claims 21, 22, 25 and 26 and the method for providing a resistance trait to a plant comprising introducing into said plant a construct comprising a nucleic acid sequence encoding an SCN/SDS resistance gene product of claims 71-80, and the teachings of the art, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of nucleic acids from a myriad of plants having resistance to SCN and SDS, even within linkage Group G of a soybean having both SCN and SDS resistance to identify a nucleic acid that encodes a polypeptide that confers both SCN and SDS resistance. In addition, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to further isolated a soybean *Rhg4* gene capable of conveying *Heterodera glycines*-infestation resistance that is located within a quantitative trait locus. In addition, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to overcome the dominance of the *Rhg1* locus on linkage Group G of a susceptible soybean plant in order to make and use the claimed transgenic plant and practice the claimed method of providing a resistance trait to a plant as claimed.

14. Claims 11-26 and 71-80 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a nucleic acid molecule encoding a biologically active SCN/SDS resistance polypeptide, a transgenic host cell comprising said nucleic acid molecule and a transgenic plant comprising said nucleic acid molecule. Applicant claims that said nucleic acid molecule comprising the nucleotide sequence of any of SEQ ID NO: 13 and a method comprising introducing into a plant a construct comprising a nucleic acid sequence encoding an SCN/SDS resistance gene encoding a protein having the amino acid sequence of SEQ ID NO: 14. Applicant additionally claims a nucleic acid molecule further comprising a *Rhg4* gene and a transgenic plant comprising a soybean *Rhg4* gene.

Applicant describes an isolated nucleic acid having the sequence of SEQ ID NO: 13 and a polypeptide having the amino acid sequence of SEQ ID NO: 14. Applicant additionally describes AFLP marker associated with the soybean *Rhg4* gene at linkage group A2 mapped by AFLP markers (pages 119-121 of the specification).

Applicant does not describe an isolated and purified nucleic acid molecule encoding a biologically active SCN/SDS resistance peptide. Applicant does not describe an isolated nucleic acid encoding a soybean *Rhg4* gene.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a

particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. It is recognized in the art that soybean cyst nematode resistance (SCN) and soybean sudden death syndrome resistance (SDS) are controlled by distinct loci within the soybean genome. While SCN resistance on linkage Group G is spatially, closely associated with SDS resistance on linkage Group G in certain soybean cultivars. Applicant describes using the soybean variety 'Forest' to produce the BAC libraries from which the putative SCN/SDS resistance polypeptide encoding nucleic acid was

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identified (page 119 of the specification). But the art teaches that the genetic background of the soybean variety 'Forest' suggests that SCN and SDS resistance is not encoded by a single locus (Chang *et al* 1997, Crop Science 37:965-971, see page 970, right column under Summary). Applicant provides no evidence that there is a single encoded polypeptide that is associated with both resistances (see Lightfoot *et al*, US Patent 6,300,541, column 20, last paragraph).

15. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

16. Claims 16, 18, 19, 25, 26 and 74-77 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 16, lines 2-3, the phrase "hybridizes to a nucleic acid sequence" is indefinite as to the metes and bounds of the claimed invention because it is unclear what the metes and bounds of "a nucleic acid sequence" are because such a sequence can encompass a nucleic acid dimer.

At claim 18, the phrase "defined as positioned under the control of a promoter" is indefinite because the metes and bounds of "positioned" is unclear.

At claim 19, line 1, the phrase "said DNA segment" lacks proper antecedence in claims 18 and 11.

Claim 25 is indefinite because it is unclear if the transgenic plant comprises the isolated nucleic acid of claim 11 further comprising an isolated soybean Rhg4 gene as in claim 23, upon which claim 25 depends. Hence, it is unclear what the metes and

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bound of the claimed invention are. In addition claim 26 is indefinite because it does not obviate the indefiniteness of claim 25, and it is unclear if the claimed seeds, parts or progeny of the plant of claim 25 comprise the isolated gene(s), or if Applicant intends to claim any, non-transgenic seeds or progeny thereof.

At claim 74(a), the phrase "a nucleotide sequence" is indefinite because it is unclear what the metes and bounds of said phrase are because such a sequence can encompass a nucleic acid dimer. In addition at (b) the phrase "substantial similar to" is indefinite because it is unclear what the metes and bounds of this phrase are.

At claim 75, line 1, the phrase "resistance characteristic" is indefinite because it lacks proper antecedence in claim 71. Claims 76 and 77 are also indefinite because said claims do not obviate the indefiniteness of claim 75.

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Conclusion


17. Claims 11-26 and 71-80 are free of the prior art, which neither teaches nor fairly suggests an isolated and purified nucleic acid molecule encoding a biologically active SCN **AND** SDS resistance polypeptide/gene product.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



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David H. Kruse, Ph.D.
30 April 2003